BPHC POLICY INFORMATION NOTICE: 97-6

Clarification of Certain Policies and Procedures for Health Centers Deemed Covered under the Federal Tort Claims Act for Medical/Dental Malpractice Liability

I. PURPOSE

This Policy Information Notice (PIN) supplements existing guidance of the Bureau of Primary Health Care (BPHC) regarding malpractice liability protection by the Federal Tort Claims Act (FTCA) for sections 329, 330, 340, and 340A grantees (termed "health centers" in this document). This guidance also applies to all health centers funded under section 330, as amended by the Health Centers Consolidation Act of 1996 (Pub.L. 104-299) and has been reviewed by the HHS Office of the General Counsel and the Department of Justice.

II. INTRODUCTION

The Federally-Supported Health Centers Assistance Act (FSHCAA) of 1992 and the FSHCAA of 1995 (Pub.L. 102-501 and Pub.L. 104-73, respectively) extended the availability of malpractice liability coverage under the FTCA to health centers and their officers, board members, employees, and certain contractors since January 1, 1993. Periodically, clarification of BPHC policies and procedures is needed to assist health centers in the implementation of the program.

III. SCOPE OF THE PROJECT

Only acts and omissions related to activities within the scope of the approved Federal project, as defined in the Notice of Grant Award are covered. BPHC PIN 96-14, June 3, 1996, outlines the core elements of the scope of the project and the procedures for updating the scope of the project. An accurate account of the scope is important since the HHS Office of the General Counsel or Department of Justice may request a copy of the grant application or other pertinent documentation to verify that a particular activity was within the scope of the project.

IV. DUAL COVERAGE

BPHC PIN 96-7, issued April 23, 1996, stated that dual malpractice liability coverage (both FTCA and private malpractice insurance covering the same activities) would not normally be an allowable cost to the PHS grant. The BPHC acknowledged that there may be situations where temporary dual coverage during a phase-in period would be financially beneficial to the health center and the Federal Government. For example, dropping private policies for one half the physicians 1 year and the remainder the next, may be necessary if the cost of tail insurance is too high for the health center to pay all in one year. In this case, by phasing-in its providers, the health center receives some savings the first year and realizes full savings once all providers are under the FTCA.

However, the BPHC is concerned that some deemed health centers may still be at a point of deciding whether FTCA coverage would be beneficial to the health center. More than 6 months has elapsed since BPHC initially notified grantees regarding the need to review their malpractice liability protection needs and determine the best means to satisfy that requirement. Dual coverage does not allow health centers to reduce the expenditure for malpractice insurance and use the saving for health services delivery. Therefore, deemed health centers must terminate any private malpractice insurance policies which create dual coverage by February 28, 1997. If the health center is unable to make a decision or obtain any required gap or wrap-around insurance by this deadline, the health center should request withdrawal of their deemed status and consider reapplication at a later date. Of course, a malpractice claim based on acts or omissions that occurred during the time period the health center was deemed remain covered by FTCA.

Any deemed health center that requires continued partial dual coverage due to phase-in or other issues, shall request approval in writing, with adequate justification, to the Director, BPHC, through the Regional FTCA Coordinator at its respective HRSA Field Office in order to avoid a disallowance.

V. HEALTH CENTER RE-DEEMING

Deemed health centers interested in maintaining FTCA coverage will be required to re-apply using the application in PIN 96-7, issued April 23, 1996, at the end of their project period (i.e., submitted with the competitive PHS grant application) starting in FY 1998.

VI. VERIFICATION OF FTCA COVERAGE

The BPHC receives numerous requests for verification of coverage under the FTCA for individual health care practitioners. Since FTCA coverage is conveyed to the individual practitioner by virtue of employment or certain contractual relationship with the health center, the name of the health center would expedite these requests. The health care practitioner should write the name of their employing health center on the "Release of Information" form provided by the hospital, managed care organization, etc.

VII. INDEMNIFICATION OF OTHER ENTITIES

The BPHC is aware that many managed care organizations, State/local governmental entities, etc., insist upon hold harmless clauses in contracts with potential providers. However, there is no statutory basis for extending FTCA coverage to those other entities in such situations. Health centers should be very cautious in entering into such agreements. Section 7 of the FSHCAA of 1995 which requires, under penalty of losing Medicare and Medicaid reimbursement, managed care plans to accept FTCA as meeting whatever malpractice coverage requirements such plans require, should assist the health center in resolving any such matters.

VIII. RISK MANAGEMENT

On-going risk management is essential to the provision of quality health care services. Private malpractice insurance companies have traditionally provided risk management services ranging from minimal to comprehensive. As deemed health centers have migrated to FTCA coverage as the means of malpractice liability protection, there has been concern of the potential loss of risk management services. The BPHC is committed to assuring that health centers continue to have the availability of risk management services. However, the BPHC is unable to bear the full burden of cost and expects, as health centers begin to realize savings in malpractice insurance costs due to coverage under the FTCA, re-investment of some of the savings to target risk reduction.

Although the BPHC is aware that the majority of private malpractice insurers are bundling risk management services with "gap or wrap-around"policies sold to health centers as a companion to FTCA coverage, the following are some specific steps being taken by BPHC:

1. The BPHC is entering into an Interagency Agreement with the Armed Forces Institute of Pathology, Division of Legal Medicine, for the dissemination to all health centers of their periodical named the "Open File". This document, which is published once a year, is devoted solely to the discussion of risk management issues and offers five credits of continuing medical education.

2. Individually tailored risk management assessment and assistance is available, on a limited basis, through the BPHC Technical Assistance program. Specific requests should be relayed to the Division of Health Service Delivery in the appropriate HRSA Field Office.

3. The BPHC has provided funding to the National Association of Community Health Centers to provide health centers with: (1) risk management training and education and (2) limited risk management consultation services via telephone.

4. Support, as an allowable cost, the purchase of separate private risk management services on the open market by health centers.

IX. FTCA QUESTIONS and ANSWERS

FTCA Coverage Issues

1. What does FTCA cover?

Services provided to health center patients within the scope of the approved Federal project (includes health center satellite clinics) and official duties of the individual (i.e., not moonlighting) qualify for FTCA coverage. Individuals accessing care at health center facilities, including the initial visit, are considered health center patients. Moreover, care given to health center patients at local hospitals as part of the continuum of care is also covered.

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In addition, certain services provided to non-health center patients as outlined in the Federal Register Notice issued September 25, 1995, are covered. Health centers which are not certain about whether a particular arrangement regarding non-health center patients are covered under the FTCA should request a particularized determination from the Director, BPHC.

2. Who is covered by FTCA?

Health center officers, board members, all employees (full-time and part-time), full-time contractors, and part-time (less than 32 1/2 hours per week) contractors providing family practice, general internal medicine, general pediatrics, or OB/GYN. In addition, contractors are required to be licensed or certified health care practitioners.

However, in the case of non-covered individuals (e.g., volunteers physician, part-time contract dentists, etc.) providing services within the scope of the project, the health center remains covered under FTCA, while the individual is not. Moreover, FTCA does not cover any moonlighting by health center health care practitioners.

3. How is employee defined?

There is no specific definition or reference to standards in the determination as to whether a person is an employee in FTCA. Although, IRS Publication 15 - Circular E, Employer's Tax Guide and IRS Publication 937 - Employment Taxes may provide useful information on employee or contractor status, the courts have not mandated the use of IRS standards.

4. Are part-time "locum tenens" providers covered if they are hired as employees for short term practice coverage?

All employees (full and part-time) qualify for FTCA coverage.

5. Should the contract with a health care practitioner be in written form to be covered by FTCA?

Yes. A written employment agreement/contract that clearly spells out the duties and responsibilities of the individual will minimize any potential confusion regarding whether the individual works for the health center and whether the activities performed are within the scope of their employment with the health center if a claim is filed. As a consequence, the determination of whether a person meets the criteria for individual coverage under FTCA is greatly facilitated.

6. How do you maintain FTCA coverage for employees when they are added or dropped?

FTCA coverage is conveyed to the individual practitioner by virtue of working for the health center. Therefore, the BPHC will not maintain lists of employees at the health center. In case of a claim, the BPHC will verify that the individual was employed at the health center at the time of the incident.

7. How does FTCA cover hospital and emergency room admissions?

In-patient hospital care to health center patients is considered part of the continuity of care of the patient and is covered by FTCA. In addition, if the hospital requires as a condition for receiving hospital privileges that the physician periodically take hospital call for admissions or emergency room coverage, then these activities are also covered under FTCA.

8. Are health center providers covered for teaching activities?

The health center and its covered health care practitioners are covered under the FTCA for teaching activities (including medical students, residents, nursing students, etc.) within the health center's facilities. The student or resident is not covered by the FTCA. Moreover, time spent by health center practitioners in non-health center facilities such as hospitals supervising the care provided by students/residents to non-health center patients is

not covered.

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What, if any, research is covered by FTCA? Should these activities be specifically noted in the scope of project?

Health centers are only protected for malpractice liability by the FTCA. Clinical research in the context of patient care conducted by health center health care practitioners with health center patients qualifies for FTCA coverage. Research with non-health center patients is not covered by FTCA.

10. Does FTCA coverage extend to supervision of the local Emergency Medical System (i.e., ambulance service) in rural communities?

No.

11. What are the limitations of FTCA coverage as opposed to comprehensive private plans? Is the $1.0 million/$3.0 million limit required by the local hospital met?

FTCA coverage is comparable to an occurrence type of malpractice policy and does not have a specific coverage limit with a monetary cap. Therefore, any coverage limits required by other organizations, such as hospitals, is met. For example, the $1.0 million each claim/$3.0 million annual aggregate occurrence is met since FTCA would, as appropriate, provide for the payment of any damages awarded as a result of a settlement or judgment sums in excess of that amount.

12. If a patient contracts an illness (AIDS, TB, etc.) from a health center physician, is the physician covered? Is the health center?

FTCA only provides for malpractice liability protection. Unless it is alleged that the infection was transmitted as a result of negligent patient care, FTCA coverage does not apply.

13. How much detail must a health center provide in its "scope of the project" to ensure FTCA coverage? For example, if the health center says it provides family planning services, will it be covered for Norplant or must it specify Norplant in its scope of coverage?

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Health centers are not required to list every specific medical procedure provided within an accepted set of services. In the example cited, contraception services are accepted as part of family planning services. Exhibit B in the BPHC Single Grant Application is the template for the level of detail necessary for delineating the scope of services.

14. In addition to grants under the Community Health Center (Section 330) and Health Care for the Homeless (Section 340), my health center sees patients as part of the HIV Early Intervention grant (Ryan White Title IIIb). Are these services covered under FTCA?

Services supported with funds under Ryan White Title IIIb qualify for FTCA coverage if those activities are part of the scope of the Section 330 or 340 project.

15. Although not required by the hospital, our health center physicians voluntarily take hospital call and periodic emergency room coverage. Are these activities covered under FTCA?

As specified in regulations published in the Federal Register, May 8, 1995, FTCA coverage is only applicable if hospital call or emergency room coverage is required by the hospital as a condition of obtaining hospital admitting privileges.

16. If a health center is part of a network, what impact will that have on FTCA coverage? For example, if the network employs the health care practitioners and assigns them to work in the health center, is the entity covered under FTCA? Are the individual health care practitioners covered?

Health centers are covered for the activities within the scope of the approved Federal project, but only the employees and certain individual contractors of the grantee or subrecipient can qualify for FTCA coverage. Therefore, in situations where the deemed health center contracts with another organization (a network in this example) to provide staffing for the health center, these providers do not qualify since they are employed by the other entity and not the deemed health center.

7. Are the May 8, 1995 regulations and the clarifications contained therein retroactive? If so, to what date?

The regulations issued on May 8, 1995, were interpretive in nature and thus are retroactive to the start date of the program of January 1, 1993.

18. What is the effective date of FTCA coverage? Is it the date the health center requested on the deeming application, or the date noted in the deeming letter?

The effective date of FTCA coverage is noted in the deeming approval letter. The date requested by the health center may not match the actual effective date due to the time necessary to process an application.

19. Are there circumstances when suits brought against the health center based on indemnification clauses in a contractual agreement are covered?

No. The BPHC is aware that many managed care organizations insist upon aa indemnification (hold harmless) provision in contracts with potential providers. However, there is no statutory basis for providing such coverage under FTCA.

20. Does FTCA cover any costs of health centers relating to pre-litigation or pre-filing negotiations with the injured party or his/her attorney?

No.

FTCA Claims Process

1. What process does an FTCA covered claim follow?

Malpractice claims against the Public Health Service must be filed with the Claims Office. After gathering copies of the medical records and other documents, the Claims Office refers the case to the Quality Review Panel (QRP) which is composed of clinicians representing the PHS agencies.
The QRP arranges for a peer review of the case, discusses the case at its monthly meeting, and makes a determination whether the standards of care were met

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in the case. The QRP determination is transmitted to the Claims Office. Then the Claims Office makes a recommendation to the Department of Health and Human Services (HHS) Office of the General Counsel (OGC) to deny the claim or settle. The OGC makes the final decision. If the case is denied or a settlement is not reached, the claimant has up to 6 months to file suit in Federal District Court.

2. What role do health centers play in this process?

When a malpractice claim is filed, the Claims Office will request copies of the medical record, a narrative statement of the incident from the health center, and pertinent statements from any witnesses. Furthermore, the health center will be asked to perform an in-depth review of the claim using a standard format. This information is crucial in assisting the QRP in the determination of the medical merits of the case.

3. How is an incident reported? Is there a special form for reporting?

There is a Standard Form 95 for making a claim under FTCA. The form is available from the HRSA Field Office or the Claims Office (see BPHC PIN 96-7 for addresses).

4. When a malpractice case has been filed, will the case be handled by lawyers from the Department of Justice with a background in malpractice?

Malpractice claims filed against the Public Health Service under the FTCA are processed by the HHS Office of the General Counsel and the Department of Justice. The delegated authority for HHS lies with experienced malpractice attorneys within the Business and Administrative Law Division and specifically with the Litigation Branch. The Department is responsible for the defense of all litigation arising from acts or omissions covered under the FTCA. Within the Department of Justice, a case would ordinarily be assigned to a United States Attorney's Office where it would be handled by an Assistant U.S. Attorney; occasionally, attorneys from the DOJ Civil Division's Torts Branch would be involved. In any event, Torts Branch attorneys would provide overall guidance to the Assistant U.S. Attorney's in consultation with attorneys from HHS's Office of the General Counsel.

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5. What assurances do I have the Department of Justice will look after the interests of the health center and provider?

As part of their responsibility to protect the interests of the United States, the Department of Justice has been defending National Health Service Corps providers in health centers for over 20 years. Their record to date has been supportive.

6. The statute of limitations for filing an FTCA claim is 2 years. Will coverage be available for pediatric cases where State law allows for cases to be filed up to age 18?

State law has no applicability. Under the FTCA, a claim must be presented within 2 years after the claim accrues. Federal law incorporates a "discovery" rule for determining claim accrual or starting date for the statute of limitations. If a claim is presented within 2 years after it accrues, the claimant must file suit within 6 months after the claim is denied. If the claim is not denied, the claimant may file suit at any time after 6 months elapse.

7. If a claim is settled, will the health center be financially responsible for any portion?

The FTCA removes the health center and any individual as a named party and substitutes the Federal Government. As a consequence, the health center is not financially liable for any claims accepted under FTCA.

8. What action is taken against the provider if the provider is found to be at fault in a malpractice claim?

The initial actions are the responsibility of the health center. There is an expectation that health centers will undertake their own internal review of claims and take necessary steps to reduce the risk in the future. However, there is a provision within the FTCA legislation which allows for a full and fair hearing by Department of Justice before it can terminate FTCA coverage of a health center or an individual who has an unacceptably high rate of claims or poses a liability risk in any of several other specified ways.

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Miscellaneous

1. What must a health center do to be deemed?

   The health center must submit a deeming application (contained in BPHC PIN 96-7, issued April 23, 1996) to the Regional FTCA Coordinator in the appropriate HRSA Field Office.

2. Will there be guidance forthcoming related to the types of policies and procedures required in Section III(Risk Management) of the deeming application?

   The requirements in the BPHC Program Expectations for Community and Migrant Health Centers provided the template for the type of policies needed to meet this condition of deeming. It is expected that this document will be updated this year to reflect changes in the health care environment.

3. What steps should a health center take after deeming?

   After deeming, the health center needs to: 1) make sure that any gaps in FTCA coverage are filled by private gap or wrap-around insurance policies, 2) purchase tail insurance, if required, and 3) terminate private malpractice insurance policies which create dual coverage.

4. If an outside agency (JCAHO, NCQA, etc.) reviews a health center and finds some deficiencies, could that lead to a de-deeming process?

   No. The deeming performed by BPHC is final and binding upon the Secretary, Health and Human Services and the Attorney General. However, health centers that have serious clinical deficiencies uncovered by the accreditation process or the BPHC Primary Care Effectiveness Review will be in non-compliance with BPHC Program Expectations and at risk for de-funding. FTCA coverage would terminate after a health center is de-funded by the BPHC.

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3. What impact will FTCA have on Federal grant dollars?

The FTCA program will not have any effect on the base funding of health centers. Furthermore, any savings realized by the health center participating in the program, remain at the health center for use within the scope of the project.

4. Are there requirements/restrictions on the tail and gap insurance (including wrap-around) policies that a health center can purchase when covered with FTCA?

There are not restrictions on gap or wrap-around policies. However, you must make sure that these policies clearly state that they do not cover activities approved for FTCA. This protects the health center from being in a situation of dual coverage for the same activity.

5. Has the Bureau worked with a private insurer to provide wrap-around coverage?

The BPHC has had numerous discussions with insurers regarding wrap-around coverage. There are several companies which are offering this product. However, the Bureau is not endorsing any particular company.

6. Private malpractice carriers frequently package risk management services with their policies. If a health center elects to be covered by FTCA and a private carrier un-bundles the risk management services, will the cost of the risk management services be an allowable cost?

Yes.

7. Will the Bureau develop a document addressing the concerns of hospitals and other private sector providers with whom health centers interact with? For example, FTCA coverage is not always understood or readily accepted by hospitals granting provider privileges.

The BPHC has provided supplemental funding to the National Association of Community Health Centers to develop a comprehensive, explanatory FTCA pamphlet with a target audience of hospitals, managed care organizations, etc.

8. What is the process when a payor refuses to accept FTCA as malpractice insurance coverage?

In situations where a hospital, managed care organization, or other entity refuses to accept FTCA coverage as meeting any requirement for malpractice liability protection, the Regional FTCA Coordinator should be contacted immediately. The BPHC will contact those entities directly in an effort to resolve the issue. If necessary, we will engage the efforts of the HHS Office of the General Counsel to come to resolution.

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